

**IX. 510(k) Summary****JUN - 2 2004**

**SUBMITTER:** DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02780

**CONTACT PERSON:** Lisa A. Gilman

**DATE PREPARED:** May 6, 2004

**CLASSIFICATION NAME:** Appliance, Fixation, Spinal Interlaminar  
Orthosis, Spinal Pedicle Fixation

**PROPRIETARY NAME:** Summit OCT Spinal System

**PREDICATE DEVICES:** Summit OCT Spinal System (K002733, K010681,  
K013222, K022190, K030103)

**DEVICE DESCRIPTION:** Addition of 3.5mm rod to the Summit OCT Spinal  
System.

The Summit OCT Spinal System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

**INTENDED USE:** The indications for use for the modified devices described in this submission are the same as those for the Summit OCT Spinal System (K022190). The indications are as follows:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput – T3), the Summit Occipito-Cervical-Thoracic (OCT) Spinal System is intended for:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlanto/axial fracture with instability
- occipitocervical dislocation

- revision of previous cervical spine surgery
- tumors

The occipital bone screws are limited to occipital fixation only.

The use of the minipolyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The Songer Cable System, to be used with the Summit OCT Spinal System, allows for wire/cable attachment to the posterior cervical spine.

The Summit OCT Spinal System can also be linked to the ISOLA, TiMX, MONARCH and MOSS MIAMI Systems using the dual wedding band and axial connectors, and via dual diameter rods.

#### MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

#### PERFORMANCE DATA:

Performance data were submitted to characterize the modified Summit OCT Spinal System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN - 2 2004**

Ms. Sharon Starowicz  
Regulatory Affairs Director  
Depuy Spine  
325 Paramount Drive  
Raynham, Massachusetts 02767

Re: K041203  
Trade Name: Modified Summit OCT Spinal System – Additional Components  
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050  
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminar Fixation Orthosis  
Regulatory Class: Class II  
Product Code: MNI, KWP  
Dated: May 6, 2004  
Received: May 7, 2004

Dear Ms. Starowicz:


We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**III. Indications for Use**

510(k) Number (if known): K041203

Device Name: Modified Summit OCT Spinal System

## Indications For Use:

The indications for use for the modified devices described in this submission are the same as those for the Summit OCT Spinal System (K022190). The indications are as follows:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput – T3), the Summit Occipito-Cervical-Thoracic (OCT) Spinal System is intended for:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X  
(Per 21 CFR 801.109)

Miriam C. Provost  
(Division Sign Off)

Division of General, Restorative,  
and Neurological Devices

DePuy Spine, Inc.  
Special 510K

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